

Response
Applicants: Rudy Mazzocchi et al.
Serial No.: 10/051,565

Attorney Docket: MVA1001USC2

REMARKS

Claims 1 to 9 are pending. Reconsideration and allowance of all claims is respectfully solicited in light of the following remarks.

Filing Date – Request for Corrected Filing Receipt

Applicants filed a Request for Corrected Filing Receipt on March 12, 2002 to request confirmation of the correct filing date of this application as --January 18, 2002--. The outstanding Office Action incorrectly lists the filing date of this application as "January 16, 2002." Correction is requested.

Information Disclosure Statements

Regarding the Information Disclosure Statement submitted with the filing of the application on January 18, 2002, Applicants note that the Examiner has not acknowledged consideration of the "Other Documents" on this record by returning an initialed and dated copy of the Form PTO-1449 submitted therewith. Applicants also note that the Examiner stated that certain of the "Foreign Patent Documents" listed on this Form PTO-1449 were "not in the file." Accordingly, submitted herewith is a copy of the Form PTO-1449 from the January 18, 2002 Information Disclosure Statement, together with copies of the previously missing "Foreign Patent Documents." The Examiner is requested to consider these currently submitted Foreign Patent Documents and all of the originally submitted Other Documents and to return an initialed and dated copy of the Form PTO-1449 to confirm consideration of all these documents on this record.

Regarding the Supplemental Information Disclosure Statement submitted on September 4, 2002, Applicants note that the Examiner did not return an initialed and dated copy of the Form PTO-1449. The Examiner is requested to

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consider these documents and to return an initialed and dated copy of the Form PTO-1449 to confirm consideration of these documents on this record.

Rejection under 35 U.S.C. § 103

Claims 1 to 9 are rejected under 35 U.S.C. § 103(a) as unpatentable by U.S. Patent No. 5,071,407 to Termin, et al. ("Termin") in view of U.S. Patent No. 5,556,389 to Liprie. The Examiner's rejection is respectfully traversed. Neither Termin nor Liprie, taken separately or together or with any other reference of record, teaches or suggests the presently claimed method or system.

Termin describes a body implantable apparatus comprising a fixation element attached to a diagnostic or treatment device to fix the device within a body cavity (col. 2, line 20 – col. 3, line 57). The fixation element may be a braided self-expanding tube (tubular fixation element 22, col. 3, lines 42 – 65, FIGS. 1 – 4; fixation element 42, col. 5, line 59 – col. 6, line 18, FIG. 5; fixation element 60, col. 6, lines 19 – 32, FIG. 6) that attaches to a *distal* end of the diagnostic or treatment device. The fixation element may alternatively attach to a *proximal* end of the diagnostic or treatment device (fixation element 60, col. 6, line 33 – col. 7, line 27, FIG. 7) and may be of a material that will break down from bodily fluids and assimilate to permit removal of the diagnostic or treatment device (catheter 62, col. 7, lines 12-27). Such material would frustrate the intent of the present claims to withdraw the filter and contained debris from the patient's vessel. The fixation element may be of a plastically, rather than elastically, deformable material, without any restoring force (fixation element 90, col. 7, lines 38-48, FIG. 8). Termin does disclose that, for permanent or long-term device fixation, a fluid-inflatable balloon may plastically expand the fixation element to ensure "the absence of interference with passage of blood or other fluids" (fixation element 90, col. 7, line 49 – col. 8, line 9, FIGS. 9 and 10). The Termin fixation

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element may permanently attach to a *medial* portion of the diagnostic or treatment device in a cylindrical form with open proximal and distal ends (col. 8, lines 10 to 40, FIG. 11), "to reduce disruption of or interference with passage of blood through the vessel." The fixation element may be a distal coil (flexible fixation element 112, col. 8, line 41 – col. 9, line 20, FIGS. 12 – 14) for acute fixation. Termin never describes or suggests the fixation element as a blood filter. On the contrary Termin emphasizes "[t]he open weave or open mesh construction" of the fixation element for the purpose of minimizing fluid entrapment so that infection at the fixation site is not promoted (col. 3, lines 51 – 57). Termin's description of the fixation element as a "permanent" installation (col. 9, lines 23 – 31) would frustrate the intent of the present claims to remove the expandable filter from a patient.

Liprie describes a method and apparatus to alleviate a bodily conduit constriction, such as a stenosis, and prevent restenosis. Liprie never describes filtration of emboli from blood with his apparatus, but teaches that elastic membranes can seal the catheter after removal of the guide wire. The membranes are placed in the catheter interior beyond the ribbed balloon to seal the catheter from the blood vessel. Filter material, such as cotton or angel foam, is provided between the membranes to wipe the guide wire as it travels through the balloon catheter, to prevent introduction of blood or other liquids into the sealed portion of the catheter. See, for example, col. 4, line 63 – col. 5, line 37 and FIG. 4. The Liprie filter is not associated with the guide wire distal region, as required by the present claims.

Neither Termin nor Liprie contain any disclosure which would motivate a person of skill in the art to combine them in any manner let alone the particular manner required by these claims. The examiner does not provide any such

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suggestion or motivation. There is no teaching or suggestion in either reference, separately or together, of the method and apparatus of the present claims.

CONCLUSION

Applicants respectfully submit that, in light of the above remarks, claims 1 to 9 are free of any grounds of rejection or objection. Should any minor matters remain prior to the issuance of a formal Notice of Allowance, the examiner is requested to telephone the undersigned to reach prompt resolution thereof.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: 9/27/04

By

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